

# Window on the Workplace 2020



## Workforce Training Needs for North Carolina's Biopharma Manufacturing Industry

Created in partnership with:



**North Carolina Biotechnology Center**

# Acknowledgements

We appreciate the contributions of the company representatives who spent time completing the survey and participating in interviews and listening sessions. Their candor as they shared ideas and suggestions on education and training needs, as well as how to attract more people to life science careers in North Carolina, made this study possible. Their input allowed us to gain an understanding of the needs of the industry and develop this report.

NCBiotech and NCBIO recognize the diligence of the following individuals in study design, collecting and analyzing data, and reviewing the following report:

## NCBiotech

**Laura Rowley, Ph.D.**

*Director, Life Science Economic Development*

**Jessica Reece**

*Research Analyst*

**Katie Stember, Ph.D.**

*Associate Director, Life Science Economic Development*

**Robin Deacle**

*Vice President, Corporate Communications*

**June Mullaney Mader, Ph.D.**

*Contract Project Manager*

*Principal Consultant, GoForward, LLC*

**Kim Marcom**

*Art Director*

**Sperry Krueger**

*Senior Research Analyst*

**Jim Shamp**

*Director, Public Relations*

**Lori Melliere**

*Outreach and Client Services Librarian*

**Elena Skrinak**

*Contract Designer*

*Owner/Creative Director, Skrinak Creative, Inc.*

---

## NCBIO

**Sam Taylor, JD**

*President*

**Bruce Kaylos**

*Consultant*

**John Wagner**

*BMF Program Manager*

**Brenda Summers, Ed.D.**

*Director of Communications*

---

## North Carolina State University

**John Balchunas**

*Workforce Director, NIIMBL*

*Assistant Director, Professional Development Programs,*

*BTEC*

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# A Letter from the Presidents

When biopharma manufacturing companies are asked why they have invested in North Carolina, they frequently cite the depth and breadth of our state's biopharma workforce. This is no accident. Since 1995, the North Carolina Biotechnology Center (NCBiotech) and the North Carolina Biosciences Organization (NCBIO) have collaborated to periodically evaluate the education and training requirements of these companies and worked to meet those needs. Window on the Workplace (WoW) 2020 continues this invaluable collaboration.

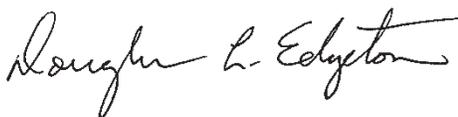
WoW has a history of revealing the essential needs of the North Carolina biopharma manufacturing industry. Indeed, WoW 2003 laid the groundwork for an investment of more than \$65 million in industry-specific education and training facilities. The study also led to the creation of NCBioImpact, a consortium of industry and academic partners that continues to work aggressively to coordinate North Carolina's biopharma manufacturing education and training programs.

Today, NCBioImpact and the academic institutions it represents are recognized internationally as premier biopharma manufacturing workforce development assets. NCBioImpact has arguably been a deciding factor in site location decisions that have contributed to a substantial share of our state's 26,800+ biopharma manufacturing employees.

WoW 2020 both confirms the success of North Carolina's biopharma manufacturing workforce development strategy and shows that North Carolina must do more to ensure continued growth and assure our state's status as an internationally recognized hub for biopharma manufacturing. Moreover, WoW 2020 strongly suggests that we will not adequately address North Carolina's biologics and pharmaceutical manufacturing workforce needs through traditional recruitment strategies. To meet future demands for labor, we will need strategies that inspire young people to understand the advantages of a career in biopharma manufacturing. We will need to reach transitioning military and veterans considering civilian career opportunities. Finally, we will need to ensure that all of our citizens, regardless of social or economic status, have opportunities to join North Carolina's biopharma manufacturing workforce.

WoW 2020 provides a roadmap for new curricula, equipment, facilities, and – above all – outreach that will be essential to advancing North Carolina's status as a world-class hub for biopharma manufacturing. As in the past, NCBiotech and NCBIO will work directly with our industry, academic, and community partners to determine the best methods for maintaining a qualified biopharma workforce. These collaborations are already underway, and we are looking forward to building on the findings of WoW 2020.

As you read this report, we encourage you to share your own ideas about improving our state's biologics and pharmaceutical manufacturing talent pipeline. Visit <https://www.ncbiotech.org/WoW> to contribute your feedback.



**Doug Edgeton**  
President & CEO, North Carolina Biotechnology Center



**Sam Taylor**  
President, NCBIO

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**We use the term “biopharma”  
in this report to describe the  
wide-ranging study cohort most  
appropriate to North Carolina.  
It encompasses biopharmaceutical  
and small-molecule pharmaceutical  
manufacturers as well as the  
manufacturers of industrial  
enzymes and R&D products.**

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# Window on the Workplace 2020

## Growth of North Carolina Biopharma Manufacturing Creates Talent Opportunities



**5,000**

*New Jobs Projected*

*Average Annual Salary of*

**\$97,575**

### North Carolina's strength in biopharma manufacturing continues to grow, with the potential to create more than 5,000 new jobs in 5 years.

To measure this growth and determine education and training needs of the industry, the North Carolina Biotechnology Center (NCBiotech) and North Carolina Biosciences Organization (NCBIO) conducted the 2020 Window on the Workplace (WoW) study. Surveys completed by a subset of biopharma manufacturers and subsequent site visits provided a window into the current workforce needs of the industry.

While performed in part to update previous iterations of WoW, this study also assessed the impacts of a wave of novel biopharma technologies such as cell- and gene-based therapies on workforce. This study captures an important inflection point in North Carolina's biopharma manufacturing landscape, demonstrates new job creation opportunities, and identifies the need to make significant upgrades to North Carolina's biopharma training infrastructure.

Currently in North Carolina, there are 80 biopharma sites that manufacture an array of products including small-molecule pharmaceuticals, monoclonal antibodies, industrial enzymes, vaccines, and cell- and gene-based therapies. The average annual biopharma manufacturing salary (\$97,575) is nearly double the state's private-sector average (\$50,863) and higher than the overall manufacturing average (\$59,834).

#### Growth:

North Carolina's sustained investment in biopharma workforce training ("NCBioImpact Training Partners" – see side panel on reverse) has supported rapid growth of biopharma manufacturing jobs (Figure 1). Future growth will be fueled by expansion of existing product lines and FDA approval of innovative technologies.

#### Challenges:

While this growth has boosted the North Carolina economy, biopharma manufacturing employers face several challenges, namely hiring and retention. In addition to overall employment growth, the following key factors contribute to these challenges:

- **New/shifting technologies** including new production processes, automation, and digitization, require additional training for both incumbent and new employees.

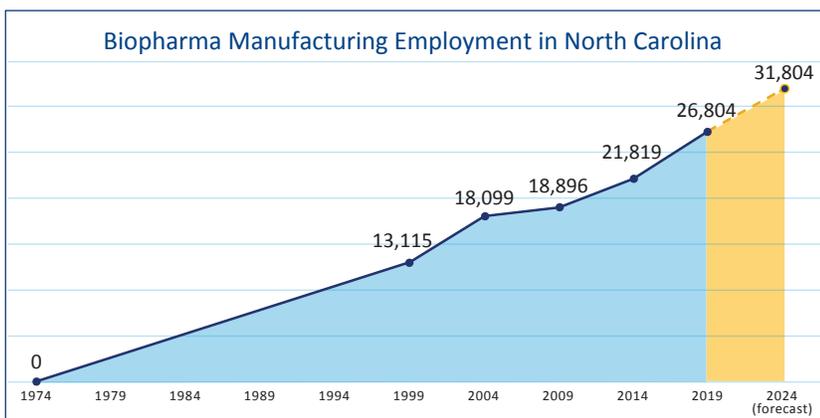


Figure 1: Biopharma Manufacturing Employment in North Carolina. Projected job creation is indicated in yellow.

Source: • # of jobs (both the factoid and graph): NCBiotech Company Directory, Window on the Workplace Survey  
• Salary: US Bureau of Labor Statistics, Quarterly Census of Employment and Wages (QCES) for NAICS 3254



- **Skill gaps** within the workforce occur due to the unique and complex nature of biopharma manufacturing. Specialized hands-on training programs and previous experience are often required to create a workforce-ready talent pool.
- **Turnover** ranged from 0-24% and averaged 8.8%, a higher rate than previous years. This turnover is largely attributed to employees moving between companies to advance their careers, as employers seek to hire experienced individuals. Respondents also expressed concerns about the retirement of baby boomers.

### Opportunities:

The WoW 2020 study informed two major opportunities to meet this increasing demand for biopharma manufacturing employees.

#### 1. Increase the Candidate Pool

**Who:** Veterans, high school students, university students, underrepresented populations, existing labor in related industries

**How:** Career fairs, awareness campaigns, scholarship programs, roadmaps to biopharma manufacturing careers

#### 2. Improve Workforce Readiness

**Build on NCBioImpact programs.** To meet the demands of this growing industry, additional personnel, equipment, and facilities are needed to bolster existing training programs.

**Create new training programs** that better enable trainees to hit the ground running. Increased collaboration with industry will help identify gaps in automation, soft skills, and problem-solving skills.

**The current surge in biopharma manufacturing is a tipping point in the sector's evolution in North Carolina. We must summon the resources to strengthen and expand N.C.'s biopharma workforce in order to drive the creation of thousands of new jobs in the next five years and beyond.**

### NCBioImpact Training Partners:

**BioNetwork** is the N.C. Community College System's life science training initiative that includes:

- BioWork certificate program
- Open enrollment and customized courses and workshops for incumbent employees and transitional workers
- Hands-on activities for students and professional development for K-14 teachers

### Biomufacturing Technology & Education Center

**(BTEC)** at North Carolina State University uses the latest biomufacturing technologies to provide hands-on learning opportunities including:

- Undergraduate minor, Professional Science Master's degrees, and both undergraduate- and graduate-level certificates
- Open enrollment and customized short courses for industry professionals
- Contract bioprocess and analytical services

### Biomufacturing Research Institute and Technology Enterprise

**(BRITE)** at North Carolina Central University provides hands-on learning opportunities including:

- Undergraduate and graduate degree programs
- Internship and on-campus research experiences
- Outreach and community programs for students and teachers

The **North Carolina Pharmaceutical Services Network (PSN)** is a collaboration between East Carolina University and Pitt Community College providing a continuum of training including:

- Oral Solid Dose short course for students and new and incumbent pharma employees
- Graduate level GMP courses
- Analytical services for government, academia, and industry

Created in partnership with:  [ncbioscience.net](http://ncbioscience.net)

## North Carolina Biotechnology Center

15 T.W. Alexander Drive | Research Triangle Park, NC 27709-3547 | [ncbiotech.org](http://ncbiotech.org)  
Asheville · Charlotte · Greenville · Wilmington · Winston-Salem

# Study Overview

## Background

### Industry Footprint & Impact

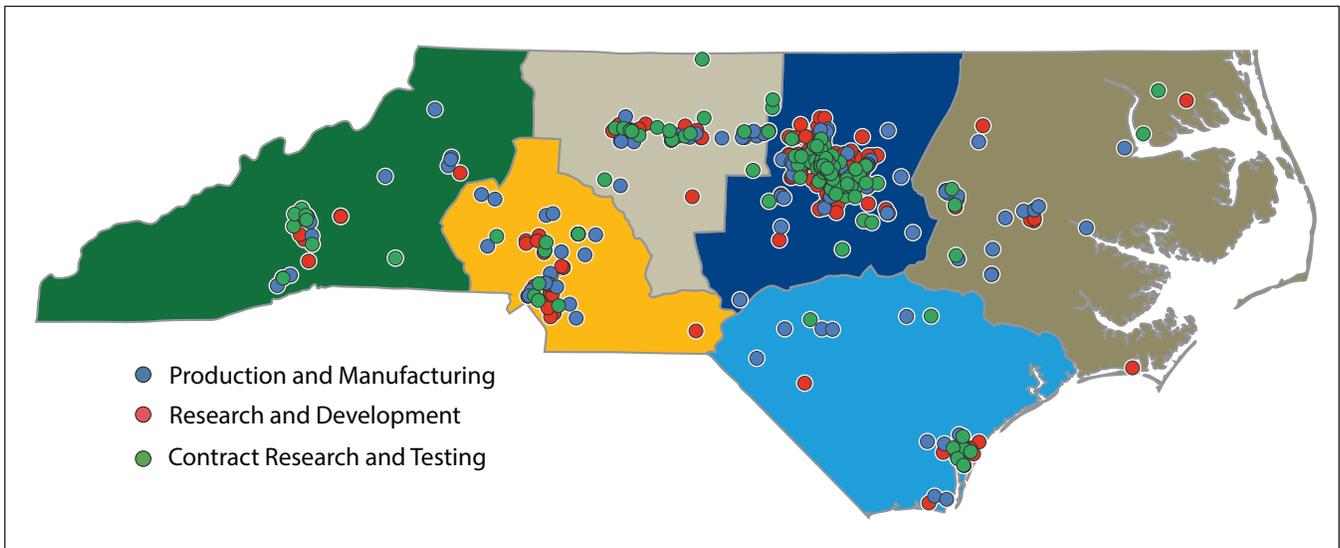
North Carolina's life science community represents a critical subsector of the state's economy due to its high-wage jobs and high-value products. In addition to biopharma manufacturing, North Carolina's diverse life science sector includes innovative research and development companies, testing and medical labs, medical device and diagnostics companies, contract research organizations, and agriculture, feedstock, and chemicals companies. While 70% of North Carolina's life science companies are located in the Research Triangle Park region, the industry has a presence statewide (Figure 1). The overall life science sector has grown from 131 companies in 1997 to more than 735 companies in 2020. Currently, the overall economic impact of the

life sciences on the state's economy includes:

- 66,000 direct employees
- \$16.7B in wages and benefits
- \$83.3B in economic output
- \$2.2B in state and local taxes

Within the biopharma manufacturing subsector, 80 North Carolina sites produce an array of products, including small-molecule therapeutics, monoclonal antibodies, industrial enzymes, and vaccines. Half of these 80 sites are located outside of the Research Triangle Park region.

In recent years, biopharma manufacturing has expanded further as novel technologies including cell-



**Figure 1:** Map of North Carolina life science companies. The Research Triangle Park region as defined by NCBiotech is shown in ■ and includes the following counties in central N.C.: Chatham, Durham, Franklin, Granville, Harnett, Johnston, Lee, Moore, Orange, Person, Vance, Wake, Warren. Map also shows NCBiotech regions: ■ Eastern, ■ Greater Charlotte, ■ Piedmont-Triad, ■ Southeastern, and ■ Western.

## Industry Footprint & Impact cont'd

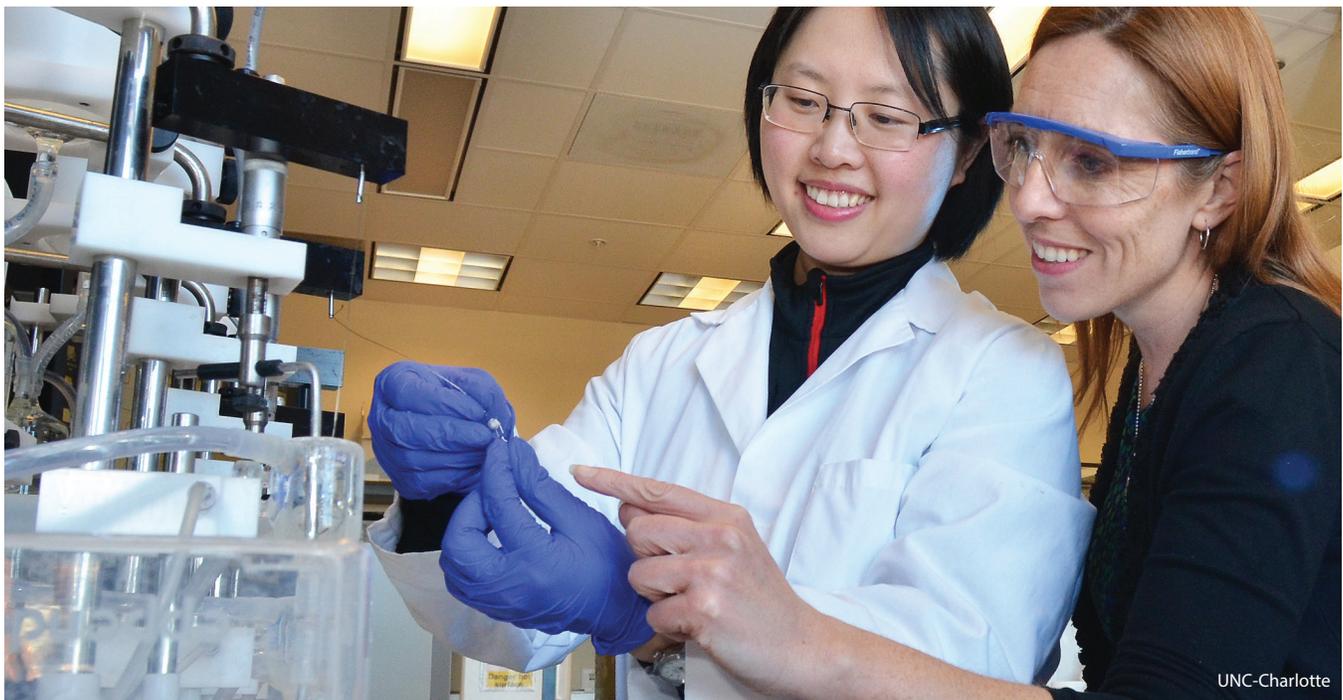
and gene-based therapies have moved from research laboratories to commercial manufacturing. For example, Pfizer's 2016 acquisition of Bamboo Therapeutics prompted an expansion of Pfizer's Sanford, North Carolina facility to accommodate gene therapy manufacturing. Additional examples of North Carolina's role in the evolution of cell- and gene-based therapies are highlighted in Figure 2.

As more companies select North Carolina for their biopharma manufacturing operations, education and training infrastructure has evolved to accommodate changing needs. One such example is NCBiotech's partnership with Pfizer to create the Pfizer-NCBiotech Distinguished Postdoctoral Fellowship in Gene Therapy; Pfizer's \$4M investment prepares North Carolina scientists for highly specialized careers in gene therapy. As biopharma companies continue to innovate, the need for specialized training programs to teach techniques associated with cutting-edge therapies will continue to grow.



*“Medicago chose to open U.S. operations in North Carolina largely due to the availability of talented, highly trained, biotech-savvy workforce. We are delighted with the quality and talent of the team we have assembled from all cross sections of the vaccine and plant-based biotech companies in the region.”*

– Mike Wanner,  
CFO and Executive VP, Operations,  
Medicago USA



UNC-Charlotte

## Gene and Cell Therapy Timeline



**Figure 2:** Timeline of key milestones in the development and commercialization of cell- and gene-based therapies. Events with North Carolina ties are noted in green, while overarching advancements in the field are in blue.

## Window on the Workplace

Determining the needs of the biopharma manufacturing industry has been an essential task since the early years of the sector's growth in the state. NCBiotech conducted the first Window on the Workplace (WoW) study in the mid-1990s (report released July 1997) and held a forum for industry representatives and educators to discuss training and education needs for the industry. At that time, there were 2,160 employees at 16 companies. That first study quantified the need for more highly skilled and trained workers, particularly bioprocess technicians.

To address the need for highly skilled workers, NCBiotech partnered with the North Carolina Community College System to develop the BioWork certificate program, which teaches the basics of chemistry, current good manufacturing practices (cGMP), and other skills identified by biopharma manufacturing companies. The first iteration of BioWork was a one-semester training program developed through a partnership between Novozymes and Vance-Granville Community College in 2001.

By 2003, the number of North Carolina biopharma manufacturing sites had grown to 56, employing more than 17,000 workers. To address industry concerns about an increasingly tight labor market, biomanufacturing representatives met with NCBIO to discuss recruitment and hiring challenges. This initial meeting led to the creation of the Biotech Manufacturers Forum (BMF) in 2004. The BMF continues to help late-clinical and commercial-phase biopharma manufacturing companies and related firms, including vendors and service providers, share information and address common concerns. Along with the BMF, NCBiotech and NCBIO worked with the UNC System, the N.C. Community College System, the Golden LEAF Foundation, and state legislative leaders to develop the Biomanufacturing and Pharmaceutical Training Consortium, now known as NCBioImpact. Today, North Carolina's biopharma manufacturing workforce has grown to more than 26,800 employees, with average salaries of \$97,575.

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## NCBioImpact: Industry-Driven Training and Education Infrastructure

NCBioImpact is a first-of-its-kind biopharma manufacturing training collaborative, created and maintained as a public-private partnership. In 2003, the Golden LEAF Foundation provided \$65M to kick start NCBioImpact with facilities and resources, existing industry supported the program through in-kind donations of equipment and employee time to assist with the set-up of facilities, and the N.C. General Assembly provided funding for ongoing education programs. The initial Golden LEAF Foundation investment established

NCBioImpact core resources including BioNetwork within the N.C. Community College System, BTEC at North Carolina State University (NC State; dedicated in September 2007), and BRITE at North Carolina Central University (NCCU; dedicated in June 2008). NCBioImpact has benefited from continued industry and state government support since its inception, and the success of this model has generated significant interest from other states and countries, inspiring the creation of similar programs around the world.

## NCBioImpact: Industry-Driven Training and Education Infrastructure cont'd

NCBioImpact training programs include:

**BioNetwork:** This North Carolina Community College System initiative delivers courses, certificates, workshops, and customized company-specific skill development in biomanufacturing, pharmaceuticals, food, beverage, and natural products at campuses throughout the community college system. Courses can be delivered at BioNetwork training facilities in Asheville or Raleigh, at local community college campuses, or on-site at the companies.



BioNetwork has served 90 companies, provided 137 customized training courses, and trained 1,252 teachers and nearly 2,300 individuals overall. In 2017–2018 alone, 67 life science companies received BioNetwork training and support.

**BRITE:** The Biomanufacturing Research Institute and Technology Enterprise (BRITE) at NCCU has 52,000 square feet of classroom and lab facilities dedicated to hands-on learning opportunities for undergraduate and graduate students. Faculty, scientists, and students work in teams to conduct drug discovery and translational research in pharmaceutical sciences. Additionally, BRITE's offerings have expanded to include professional development workshops for incumbent workers. In 2018, enrollment in BRITE programs totaled 107 undergraduate and 16 graduate students.



and academic entities have hired nearly 90% of recent BRITE graduates.

BRITE also operates an outreach program to build awareness of pharmaceutical science as a career path. Since its inception in 2008, the program has served 14,334 students and 743 teachers from 86 North Carolina counties.

Twenty BRITE undergraduates participated in a summer internship in 2018, spanning both research and industry work experiences. Industry, research,

**BTEC:** The Biomanufacturing Training and Education Center (BTEC) at NC State provides education and hands-on experience with commercial-scale biomanufacturing equipment to undergraduate and graduate students, as well as working professionals. BTEC's 82,500-square-foot facility includes pilot-scale, simulated-GMP manufacturing suites.



students through FY 2018. Additionally, BTEC provided 32 open enrollment and customized short courses to 456 industry professionals in 2017-2018, with more than 2,800 participants since 2009. BTEC also provides contract services to both industry and academic clients.

BTEC programs have enrolled more than 7,000 students since 2008 with steadily rising numbers of graduates. Placement rates in the industry reached 95% for undergraduates, and 98% for graduate

## NCBioImpact: Industry-Driven Training and Education Infrastructure cont'd

**NCPSN:** The North Carolina Pharmaceutical Services Network (PSN) joined NCBioImpact in 2017. The PSN is a partnership between East Carolina University (ECU) and Pitt Community College (PCC) that provides a continuum of pharmaceutical education and training to students and employees at new and existing companies in North Carolina and beyond.

The PSN at ECU provides laboratory-based education and training in cGMP, good laboratory practices (GLP), and analytical technology. The PSN at PCC simulates a commercial manufacturing environment



with equipment to teach oral solid dosage theory and manufacturing techniques. Since opening in 2017, more than 180 students from regional companies including ThermoFisher, Mayne Pharma, GlaxoSmithKline, and the general public have completed the Oral Solid Dose course at the PSN at PCC.

In addition to NCBioImpact's specialized training, North Carolina's higher-education institutions include many other world-renowned programs in engineering and biological sciences. Overall, North Carolina colleges and

universities graduate more than 4,600 students with degrees in biological and biomedical sciences and 4,200 students with engineering degrees annually.



## Impact of Collaboration

The success of NCBioImpact training programs is due in part to the ongoing collaboration among industry, NCBiotech, NCBIO and academic training partners, along with continued support from the North Carolina General Assembly. For example, BioWork has been expanded over the years including release of the first official manual in 2004 and a comprehensive program redesign in 2019 to meet the ever-evolving needs of the industry. BioNetwork's revised BioWork program was piloted at select community colleges in 2019, and will be fully implemented in 2020. NCBiotech and NCBIO staff meet several times a year with program leaders to discuss collaboration and training; importantly, BMF members are updated regularly. NCBioImpact training programs have been an integral part of North Carolina's effort to attract new companies and encourage the expansion of existing companies.

Additionally, BioNetwork, BRITE, and BTEC have all leveraged the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) as a resource to address the demands of emerging technologies, enhance collaboration, and increase funding. As a Manufacturing USA institute, NIIMBL is a public-private partnership dedicated to advancing biopharma manufacturing technologies and workforce development. NIIMBL grants have been used in N.C. to develop courses to address evolving training needs including automation and viral vector production for AAV gene therapy (See "NIIMBL in NC").

## Report Overview

This report describes the results of a thorough study of the workforce needs of North Carolina's biopharma manufacturing industry. Importantly, the study shows the industry has the potential to create more than 5,000 new biopharma manufacturing jobs in North Carolina over the next five years. This level of demand will challenge, and likely exceed, the output of North Carolina's existing biopharma education and training infrastructure. Survey respondents identified a need not only for more process technicians, but also for mid-level and site leadership positions.

The study also clearly depicts an industry at a technological inflection point as new cell- and gene-based therapies are commercialized. While the potential of these new technologies to address previously untreatable diseases is immense, unique aspects of their production processes will require innovative training programs.

## NIIMBL in NC

The National Institute for Innovation in Manufacturing Biopharmaceuticals

### SPIDER Network for Automation Training

(NC State): design and implement automated bioprocess test beds and hybrid online/hands-on activities for automation training for engineering, validation, operations, and quality assurance personnel.

### Preparing for the Future: A Gene Therapy

Vector Production Platform (NC State/UNC-CH): developed "cGMP Biomanufacturing of Vectors for Gene Therapy" short course for specialized hands-on training; all offerings of this course at BTEC have been full.

### Partnership for Workforce Development in the BioPharmaceutical Industry

(University of North Carolina Wilmington): established regional training, including an online classroom of supplemental modules, and capstone internships with a focus on GMP, quality and risk analysis, analytical methods, automation, validation, and advanced manufacturing technologies for community college and undergraduate students.

### Stackable Credentials to Strengthen the Pipeline to Biopharma

(NCCU/BioNetwork/Forsyth Technical CC/Alamance CC/Durham Tech CC/Vance-Granville CC): expanded articulation agreements between four N.C. community colleges and NCCU, developed on-line certificates for advanced training, and established externships for community college students. Together, supporting a seamless transition from community college to advanced certificates and/or baccalaureate degree programs.

© 2020 NIIMBL. The projects described above were developed with awards from the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) and financial assistance from the U.S. Department of Commerce, National Institute of Standards and Technology (70NANB17H002).

## Report Overview cont'd

WoW 2020 lays the groundwork for an evaluation of North Carolina's existing biopharma manufacturing training and education programs as compared to the current and pending needs of the industry. Using gap analysis and comparisons between current and required throughputs, NCBiotech and NCBIO will develop work plans, coordinate with training partners, and identify funding mechanisms to meet the changing needs of our state's biopharma manufacturing sector.

## Study Goals

Based on data collected from December 2018 through March 2019, this fourth *Window on the Workplace* study provides a snapshot of North Carolina's biopharma manufacturing companies. The survey focused on specific areas of interest including:

- Securing an overview of biopharma manufacturing companies – site locations, product types, and operations
- Assessing current and future employment – number of employees, scientific and technical areas of work, number of new hires, turnover rate, and positions that are challenging to fill
- Determining current and desired educational attainment levels across scientific and technical employees – from high school through Ph.D.
- Evaluating current recruitment and hiring practices – use of online resources, educational institutions, employee referrals, staffing firms, and other means
- Assessing company views of existing training programs to determine geographic and technical areas for the expansion of current training efforts or creation of new initiatives
- Laying the groundwork for a more comprehensive understanding of curriculum, equipment, software, and facilities necessary to prepare workers for jobs in the biopharma sector

## Study Design

For this study, biopharma manufacturing is broadly considered to include companies engaged in the manufacture of the following product types (See Appendix Tables 1-4 for full list):

- Biologics for clinical and commercial use
- Biologics for use in research and development
- Small-molecule pharmaceuticals and diagnostics
- Supplements and nutraceuticals

The WoW survey was sent to 63 biopharma manufacturing companies selected to provide a representative view of the geographic and product type diversity in the state. A total of 28 companies provided feedback, with 25 submitting survey responses.

The survey was designed to collect both quantitative and qualitative information about site activity and products; existing workforce including number of employees, positions, and education levels; growth projections; recruitment efforts and turnover; and current and future training needs and resources.

In addition to the survey, 10 companies with diverse technologies and projected growth rates were selected for on-site interviews to provide additional details about their survey responses with a particular focus on future expansions and training needs. Finally, companies participated in two focus groups to provide greater detail regarding curriculum and equipment required for effective training.

Study responses represented 17,560 of the 26,800+ biopharma manufacturing employees in the state, two-thirds of the industry's presence. In addition to information from the survey responses, NCBiotech's Life Science Intelligence research team provided supplemental data from the NCBiotech Company Directory. This report synthesizes the survey and supplemental data, including on-site interviews, to provide an overview of North Carolina's biopharma manufacturing industry.

# Study Results

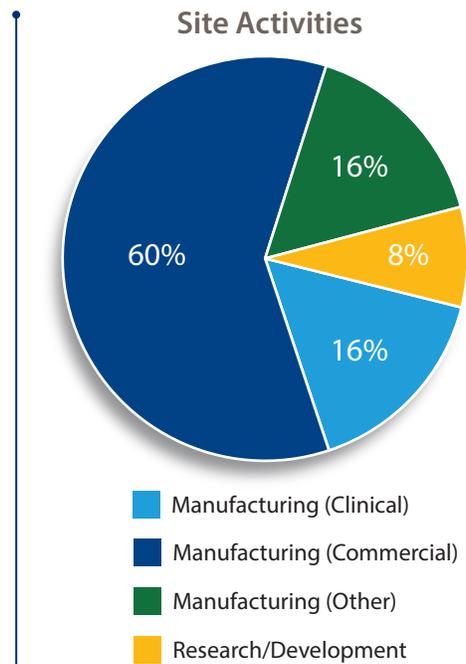
The WoW 2020 study was designed to assess the existing biopharma manufacturing workforce in North Carolina, predict changes to this workforce, and identify challenges that employers are facing to acquire and retain talent. In this section we present the study results, beginning with a snapshot of the current biopharma manufacturing industry, followed by projected growth of the industry, and finishing with challenges presented by that rapid growth.

## Existing Industry

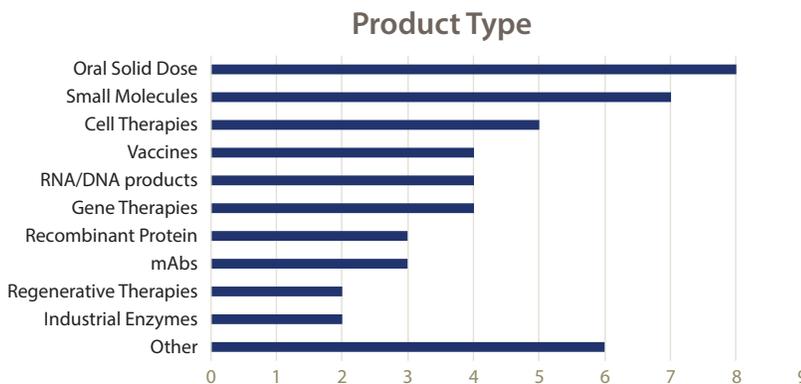
### Site Activities and Product Types

Survey respondents were asked to report both their primary site activity and the primary product being manufactured in North Carolina. As expected based on the targeted study cohort, the majority of surveyed companies reported commercial manufacturing as their main activity followed by clinical and other manufacturing. Note: Many companies perform multiple activities at a single site however, this data reflects only the reported primary activity (Figure 3).

The products most commonly manufactured by survey respondents include cell therapies and small molecules, specifically oral solid dose (tablets) (Figure 4). Other common products include vaccines, RNA/DNA products, gene therapies, recombinant proteins, monoclonal antibodies (mAbs), regenerative therapies, and industrial enzymes. Several companies reported the production of multiple product types at a single site.



**Figure 3: Survey Respondents' Site Activities.**  
Note: Business/Corporate and Manufacturing (equipment, supplies, etc.) responses were 0.



**Figure 4: Survey Respondents' Manufactured Products by Category.** Note: some companies reported more than one product type.

## Site Activities and Product Types cont'd

While the manufacture of both vaccines and traditional pharma products is expected to remain an important part of North Carolina's biopharma manufacturing industry, companies such as Pfizer are now adding gene therapy as part of their portfolio. Additionally, companies including AveXis, bluebird bio, and Collectis are establishing new facilities dedicated to the manufacture of cell- and gene-based therapies. Other companies, such as Humacyte, are fully focused on developing regenerative medicine therapies.

As quantified by several reports over the last five years, biologics-based therapeutics are increasing in prevalence and potential revenue generation. In 2014, McKinsey reported that biopharmaceuticals generate global revenues of \$163 billion, making up 20% of the total pharma market.<sup>1</sup> At more than 8%, the annual growth rate for biopharmaceuticals is double that of conventional pharma, making it the fastest-growing part of the industry. More recently, a 2018 Deloitte report stated that "biologics are predicted to comprise more than a quarter of the pharmaceutical market by 2020."<sup>2</sup> Importantly, the top 10 drug launches of 2019 included two gene therapies (Zynteglo and Zolgensma), and four biologics (Ultomiris, Skyrizi, AR101, brolocizumab).<sup>3</sup>

Biologics and other new products have made diseases, previously regarded as deadly, manageable and in some cases even curable. Gene therapy has become an increasingly important subset of the biologics market, especially in North Carolina. BIS Research recently reported that "the global gene therapy market was valued at \$1.07 billion in 2018 and is estimated to grow over \$8.95 billion by 2025."<sup>4</sup> The FDA anticipates that by 2020 it will be receiving up to 200 Investigational New Drug (IND) applications per year for cell- and gene-based therapies alone, another indication that manufacturing demands for this subsector of biopharma will be on the rise.<sup>5</sup>



*"Gene therapy manufacturing requires a highly skilled team, and Research Triangle Park is an ideal location for our continued expansion as it enables us to recruit top talent, including through partnership with local schools and colleges."*

– Eamon Fitzmaurice,  
AveXis plant controller  
February 18, 2019 announcement  
of planned expansion at new  
North Carolina facility

<sup>1</sup> McKinsey & Company – Ralf Otto, Alberto Santagostino & Ulf Schrader. December 2014. "Rapid Growth in biopharma: Challenges and opportunities." Accessed September 2019. Link: <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/rapid-growth-in-biopharma#>

<sup>2</sup> Deloitte – 2018. "2018 Global life sciences outlook: Innovating life sciences in the fourth industrial revolution: Embrace, build, grow." Accessed September 2019. Link: <https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-ls-outlook-2018.pdf>

<sup>3</sup> Fierce Pharma – Angus Liu. June 2019. "The top 10 drug launches of 2019". Accessed January 2020. Link: [fiercepharma.com/special-report/top-10-drug-launches-2019](http://fiercepharma.com/special-report/top-10-drug-launches-2019)

<sup>4</sup> Quoted from: <https://www.bloomberg.com/press-releases/2019-08-06/global-cell-and-gene-therapy-market-to-reach-11-96-billion-by-2025> Original report: BIS Research. July 2019. "Global Cell and Gene Therapy Market: Focus on Products, Applications, Regions and Competitive Landscape – Analysis and Forecast, 2019-2025" link: [https://www.reportlinker.com/p05803972/Global-Cell-and-Gene-Therapy-Market-Focus-on-Products-Applications-Regions-and-Competitive-Landscape-Analysis-and-Forecast.html?utm\\_source=PRN](https://www.reportlinker.com/p05803972/Global-Cell-and-Gene-Therapy-Market-Focus-on-Products-Applications-Regions-and-Competitive-Landscape-Analysis-and-Forecast.html?utm_source=PRN)

<sup>5</sup> <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-peter-marks-md-phd-director-center-biologics>

## Employees

WoW 2020 quantified the existing workforce of surveyed companies based on total number of employees, functional area, and educational attainment level. The total number of workers employed at surveyed companies was 17,560, with an average of 627 employees per site. On average 11.6% of positions were reported to be temporary employees or contractors. Serving as a temporary employee is one entry point for individuals seeking to break into the industry, as opportunities exist for these roles to be converted to permanent positions.

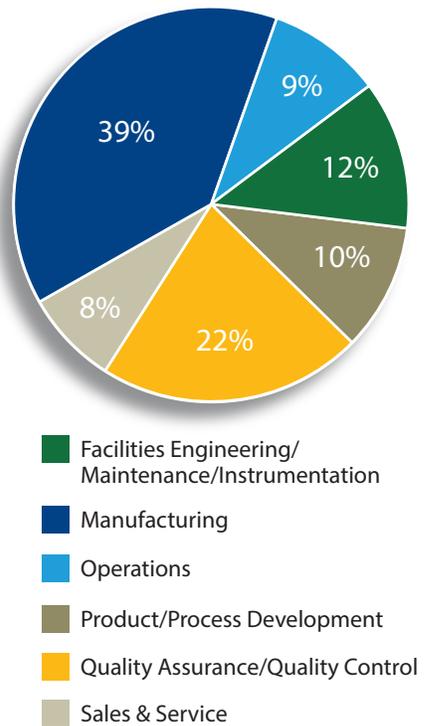
Due to the complex manufacturing processes in biopharma facilities, employees are often required to have specialized scientific and technical skills. The cumulative breakdown of scientific and technical employees by functional area revealed that manufacturing and quality assurance/quality control, at 39% and 22% respectively, made up more than half of employees at biopharma manufacturing sites. The other four functional areas (facilities engineering/maintenance/instrumentation, product/process development, operations, and sales & services) ranged from 8-12% of all scientific and technical employees (Figure 5).

### Educational Profile of Employees

The survey asked companies to report the educational attainment level of their current workforce. As functional activities vary broadly across biopharma manufacturing operations, roles were assigned to the following employment categories:

- Automation/Data Analysis/Modeling
- Customer Service/Technical Support
- Facilities Engineering/Maintenance/Instrumentation
- Manufacturing
- Operations
- Process Development/Manufacturing Sciences
- Quality Assurance/Regulatory Affairs
- Quality Control
- Research/Product Development
- Sales/Marketing
- Validation

**Scientific and Technical Employees by Function Area**



• **Figure 5:** Survey Respondents' Employee Breakdown by Functional Area.  
Note: Automation/Data Analysis/Modeling <1%, not shown here.



## Employees cont'd

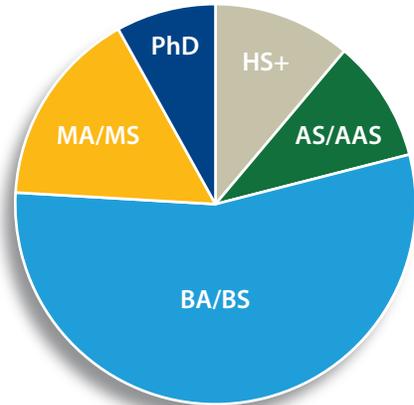
Companies selected the “percentage of scientific and technical employees at each base educational level” from the following options:

- 0-10%
- 11-20%
- 21-30%
- 31-40%
- 41-50%
- 51-60%
- 61-70%
- 71-80%
- 81-90%
- 91-100%

To provide an overview of the educational attainment levels at N.C.'s biopharma manufacturing sites, the data from all functional employment categories was combined; this data indicates that a Bachelor's degree is overwhelmingly the most common level of education for scientific and technical employees at the surveyed companies (Figure 6).

In contrast to the overall educational attainment profile, survey respondents indicated that facilities engineering/maintenance/instrumentation and manufacturing roles are filled at similar levels by HS+ (individuals who have completed high school or equivalent as well as certifications or other job-specific training, but do not possess a college-level degree) and university educated individuals (Figures 7C and 7D). As these roles make up more than half of overall positions at surveyed companies (Figure 5), the educational attainment data indicates the prevalence of opportunities in biopharma manufacturing for HS+ individuals. During interviews, multiple companies indicated that there were limited opportunities for individuals with a high school diploma alone.

Overall Educational Attainment (Weighted)



- High school with a certification or work experience (e.g. BioWork)
- Associate/Associate in Applied Science
- Bachelor of Arts/Bachelor of Science
- Master of Arts/Master of Science
- Doctor of Philosophy

Figure 6: Employees' Educational Profile, Overall.

Weighted ranks were as follows: 0-10%=1, 11-20%=2, 21-30%=3, 31-40%=4, 41-50%=5, 51-60%=6, 61-70%=7, 71-80%=8, 81-90%=9, and 91-100%=10



## Employees cont'd

Also deviating from the overall educational attainment profile, the Research/Product Development employment category skewed toward graduate degrees with multiple survey respondents reporting a significant percentage of employees in these roles having a MA/MS degree or Ph.D., compared to the overall workforce educational profile (Figure 7I). However, BA/BS degrees were still the most prevalent degree held by employees in this functional area. It is also important to note that research and product development make up only 10% of total roles at the companies surveyed, indicating that there are a relatively limited number of biopharma manufacturing positions that require a graduate level education.

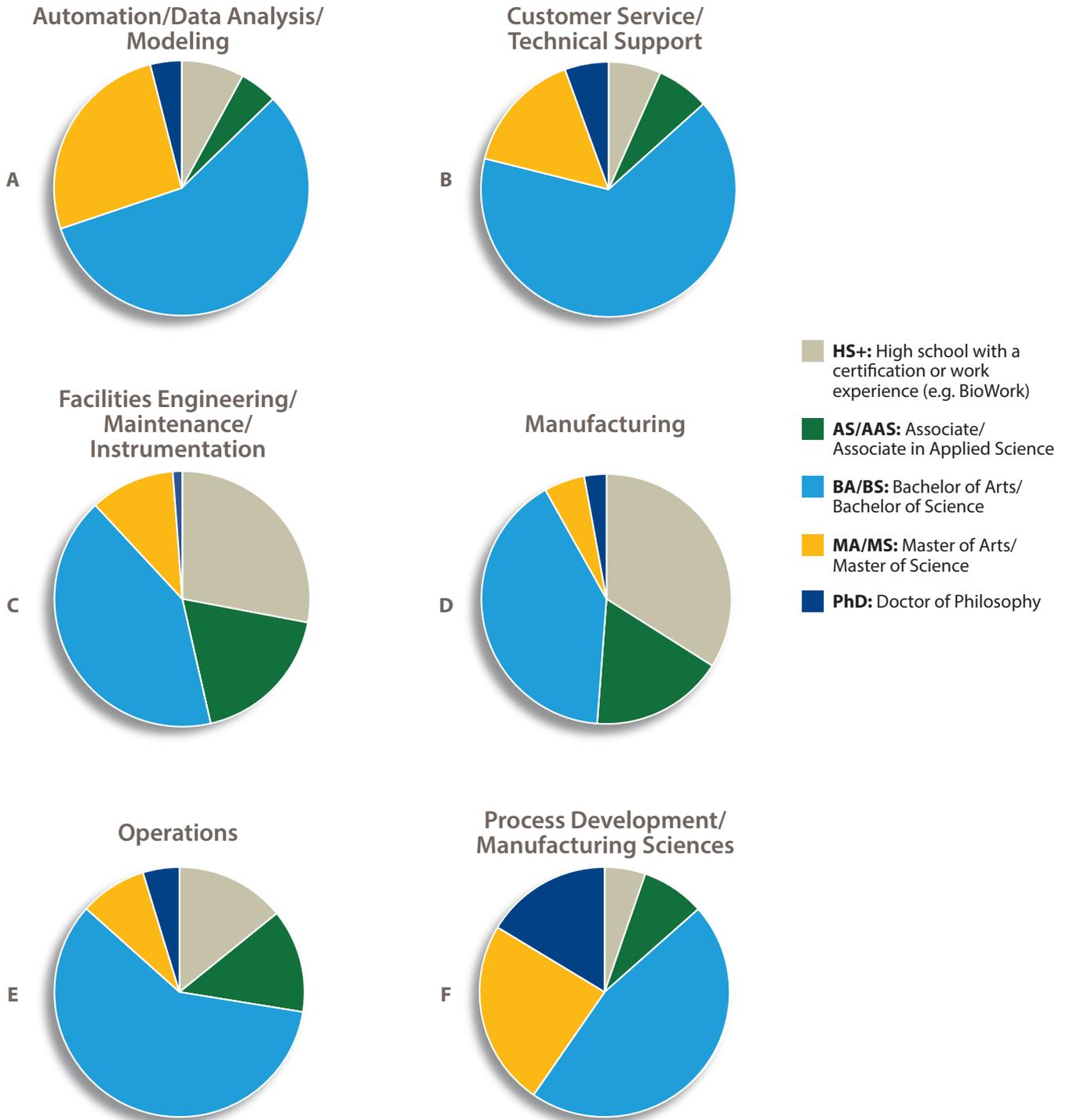
For all other employment categories (Figures 7A, 7B, 7E, 7F, 7G, 7H, 7J, 7K), representing the remaining 40% of total employment at surveyed companies, the educational attainment profile closely resembled the overall trend (Figure 6). Across all employment categories, Ph.D.s followed by AS/AAS degrees were the least reported by companies as their employees' terminal degree (Figures 6 and 7). With regard to AS/AAS degrees, these numbers

do not reflect the fact that some employees complete a bachelor's degree after their associate's and may do so while working for the company. Additionally, the greater number of university graduates with relevant degrees compared to community college graduates skews the candidate pool, resulting in more BA/BS degreed employees at N.C. biopharma manufacturing sites.

In discussions focused on educational requirements, companies often cited their desire to have a trained and knowledgeable workforce capable of "hitting the ground running." When asked if they would like to see the educational profile of their workforce change considerably in the next five years, the majority of respondents said no. Those that indicated they would prefer a shift emphasized the need for more employees with AS/AAS and BA/BS degrees to accommodate increased automation and technicality of the manufacturing processes. In light of the current low levels of unemployment (4.2% statewide), some employers have begun discussing potential changes, such as adjusting requirements for previous experience, to broaden the pool of prospective employees.



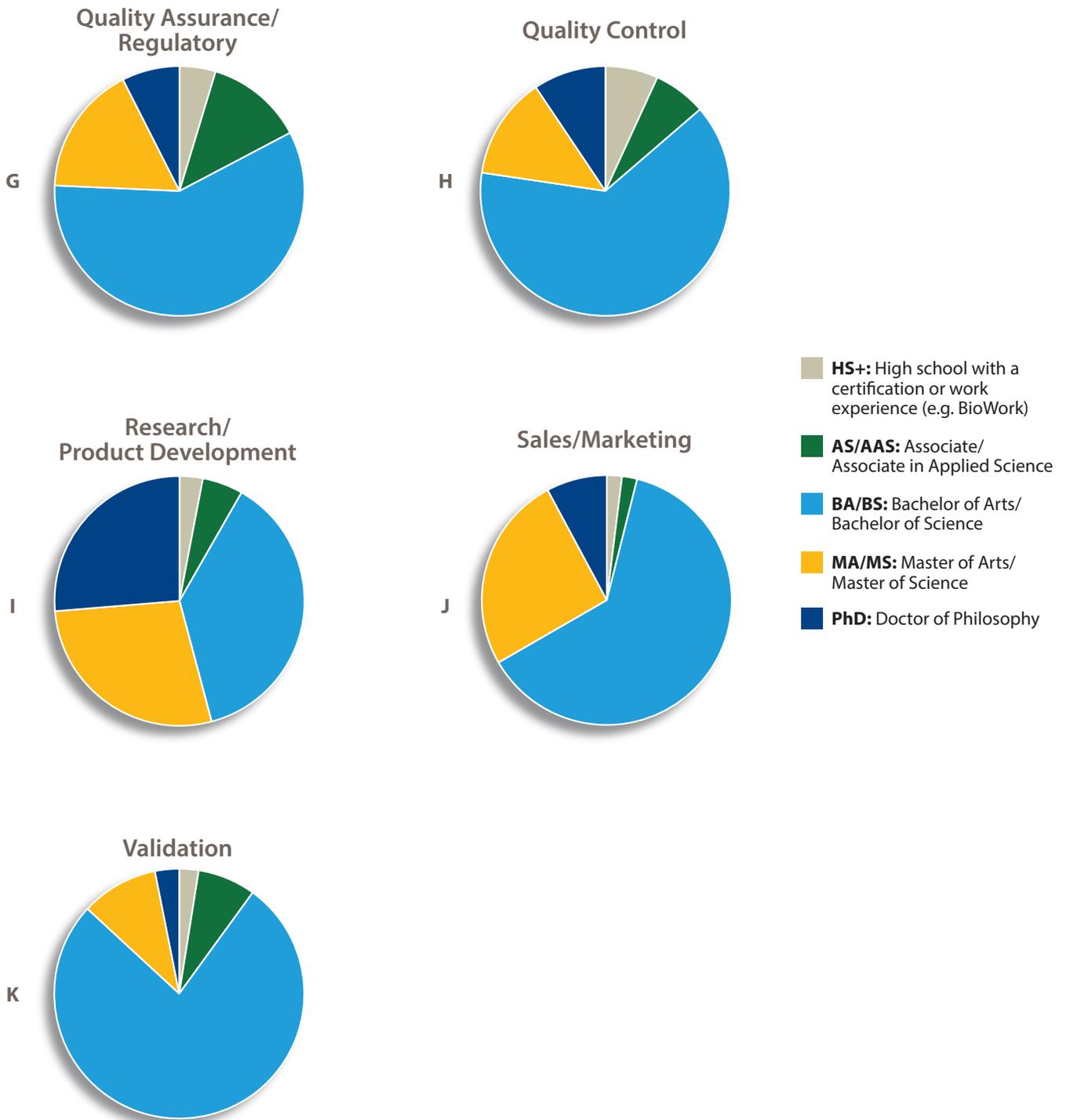
## Employees cont'd



**Figure 7 (A-F): Educational Attainment of Incumbent Employees by Role.**

Weighted ranks were as follows: 0-10%=1, 11-20%=2, 21-30%=3, 31-40%=4, 41-50%=5, 51-60%=6, 61-70%=7, 71-80%=8, 81-90%=9, and 91-100%=10

## Employees cont'd



**Figure 7 (G-K):** Educational Attainment of Incumbent Employees by Role.

Weighted ranks were as follows: 0-10%=1, 11-20%=2, 21-30%=3, 31-40%=4, 41-50%=5, 51-60%=6, 61-70%=7, 71-80%=8, 81-90%=9, and 91-100%=10

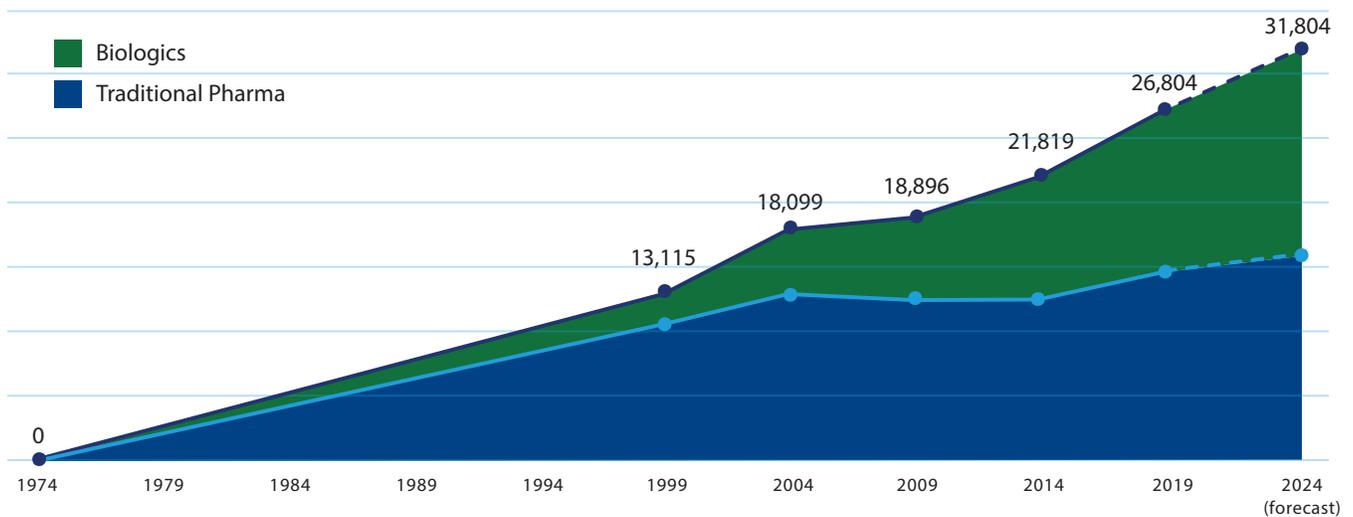
# Growth

As discussed in the executive summary, North Carolina's sustained investment in biopharma workforce training has supported the rapid growth of biopharma manufacturing jobs. Future growth will be fueled by expansion of existing product lines and FDA approval of innovative technologies. Our forecast of more than 5,000 new biopharma manufacturing jobs over the next five years is based on the expansion of existing sites as reported in this survey, as well as projected growth due to the establishment of new sites (Figure 8). Projections for the attraction of new sites were based on historical data and current inquiries. North Carolina is on track to create 2.5 times more jobs by 2024 than the number of new biopharma manufacturing jobs created in the previous decade (9,985 between 2014 and 2024 compared to 3,720 between 2004 and 2014). It is important to note that this growth only captures new job creation and does not account for hiring due to normal attrition and turnover.

Eighty-five percent of companies surveyed reported plans for either minor growth (10-100 employee increase) or significant growth (100+ employee increase) over the next five years; none of the survey respondents expect to reduce the size of their North Carolina sites during that time frame. Site visits allowed us to further quantify "significant growth" and revealed that five of these companies expect to create 200 new jobs or more, with some anticipating the addition of as many as 600 new jobs. When asked about the factors driving this

*85% of surveyed companies reported plans to add headcount in the next 5 years and zero respondents expect to reduce the size of their NC operations.*

**Biopharma Manufacturing Employment in North Carolina**

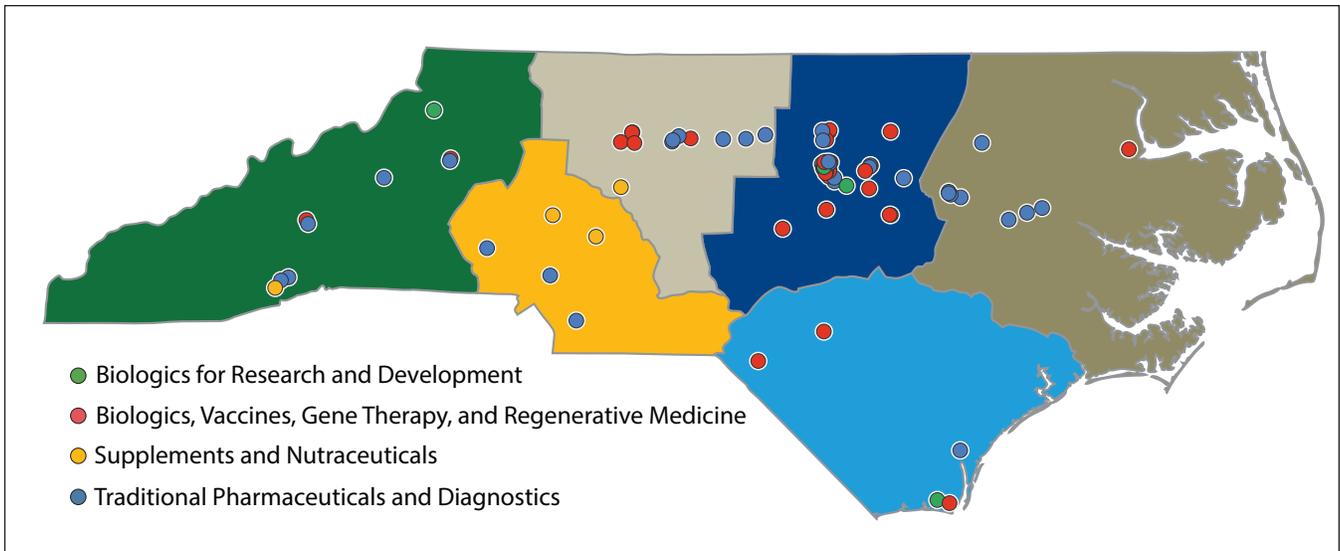


**Figure 8:** This plot shows the growth of biopharma manufacturing employment between 1974 and 2019, with forecasted employment for the next five years (WoW data) as dashed lines. Shading indicates the proportion of existing jobs and future growth contributed by traditional pharma (blue, includes traditional pharma, diagnostics, supplements and neutraceuticals) and biologics (green, includes biologics, vaccines, gene therapy, regenerative medicine, and biologics for R & D).

## Growth cont'd

growth, companies reported increased demand for existing products, the addition of new products, or both. The most frequently cited barrier to growth was access to skilled talent. Approximately 25% of the projected growth is attributed to cell- and gene-based therapy manufacturing expansions.

The substantial cluster of biopharma manufacturing companies that have located in the Research Triangle Park region have easy access to top talent, transportation via Raleigh-Durham International Airport (RDU), and a rich innovative environment. Companies who have decided to locate outside of the immediate Triangle area benefit from additional space to grow their facilities and competitive pricing, while often maintaining the ability to draw talent from the Research Triangle Park region (Figure 9). Additionally, significant investment in biopharma manufacturing training infrastructure, including the Johnston County Workforce Development Center in Clayton and the PSN in Greenville, has bolstered the local talent in the Biopharma Crescent region east of RTP (Edgecombe, Johnston, Nash, Pitt and Wilson counties).



**Figure 9:** Distribution of biopharmaceutical manufacturing companies across North Carolina. Map shows NCBiotech regions: ■ Research Triangle, ■ Eastern, ■ Greater Charlotte, ■ Piedmont-Triad, ■ Southeastern, and ■ Western.

# Challenges

**One of the most pressing challenges facing biopharma manufacturing companies in North Carolina today is the acquisition and retention of talent. That said, other challenges exist for these companies including scale-up of cell-based therapies that maintains potency and consistency of the cells, safe disposal of nitrogen-rich wastewater generated by commercial-scale manufacturing processes, and bottlenecks in the manufacturing process including sterilization of equipment, purification of products, and packaging that meets recently updated requirements.<sup>6</sup>**

**WoW 2020 assessed the current hiring, recruitment, and training practices of study participants to identify gaps and understand how North Carolina can further support the growth of these companies. Participating companies also shared turnover rates and identified positions that are especially challenging to hire and retain. Follow-up site visits with select companies revealed additional insights into company challenges. Key issues cited during interviews were identification of skilled talent, hiring the necessary talent, and retaining incumbent employees among fierce competition.**

## Turnover

Survey results revealed an average turnover rate of 8.8%, with rates ranging from 0-24%. Zero percent turnover was primarily reported by companies that very recently opened facilities in North Carolina; these companies acknowledged that their current lack of turnover is unlikely to be sustained over time. With this in mind, the reported average rate is likely an underestimate for most established sites.

Site visits revealed that most biopharma manufacturing companies are experiencing higher rates of turnover than in previous years, though a few reported consistent or even lower levels of turnover than in the past. When asked what may be driving this increased turnover, companies suggested an increasingly competitive landscape in North Carolina and the presence of new players in the market who are attracting talent with new technologies, promotions, and competitive wage and benefit packages. Numerous companies also shared concerns about the start of the “grey wave” as baby boomers, many of them longtime employees with significant institutional and industry knowledge, prepare for retirement.

Scientists, engineers, and manufacturing and maintenance positions were most commonly identified as difficult to retain. Some companies also reported difficulty retaining chemists, mechanics, formulation technicians, and employees working in safety, data, and process development.

## Hiring and Recruitment

Survey questions regarding hiring and recruitment practices were differentiated based on whether or not prior experience is required. The distinction between entry-level positions and roles requiring experience is useful because the talent pools that companies are pulling from to fill these jobs are likely very different. Additionally, outreach efforts to recruit and train workforce will differ for positions that require experience versus those that do not.

Overall, more than half of the positions filled by survey respondents within the last year required experience. However, not all experience prepares prospective employees for the requirements of shift work. Shift work in biopharma manufacturing presents one barrier for both recruitment and retention efforts as some employees may move between companies, or even out of the industry, in pursuit of a traditional work schedule.

Companies reported that the highest proportion of new employees were identified regionally, followed by within the U.S., and then internationally. While North Carolina’s regional talent pool was utilized to hire a majority of positions across experience levels, a smaller number of companies performed national searches for roles that do not require experience and no companies reported international hires for positions with no

<sup>6</sup> TEconomy Partners LLC – “Biopharmaceutical Manufacturing in the U.S.: Making Cutting-Edge Medicines Today and Leading the Way on Medicines of Tomorrow.” March 2019. Prepared for the Pharmaceutical Research and Manufacturers of America (PhRMA).

experience required (Figure 10). In interviews, employers confirmed their preference for, and success to date with regional hiring for the majority of positions. National searches are most often used to recruit experienced supervisors and managers, as well as some IT positions. Additionally, some employers use national searches to gain access to the graduates of specialized programs, such as the packaging engineering programs offered at Michigan State University and Purdue University.

The survey also asked participants to share their utilization of existing recruitment tools over the last year, again differentiating between positions requiring experience and those that do not. Companies were asked about the following commonly used recruitment resources:

- Career Fairs
- Community Colleges
- Employee Referrals/Networking
- Intern/Co-op
- Miscellaneous/Other
- Online Recruiting
- Recruiters/Staffing Firms
- Universities and Colleges

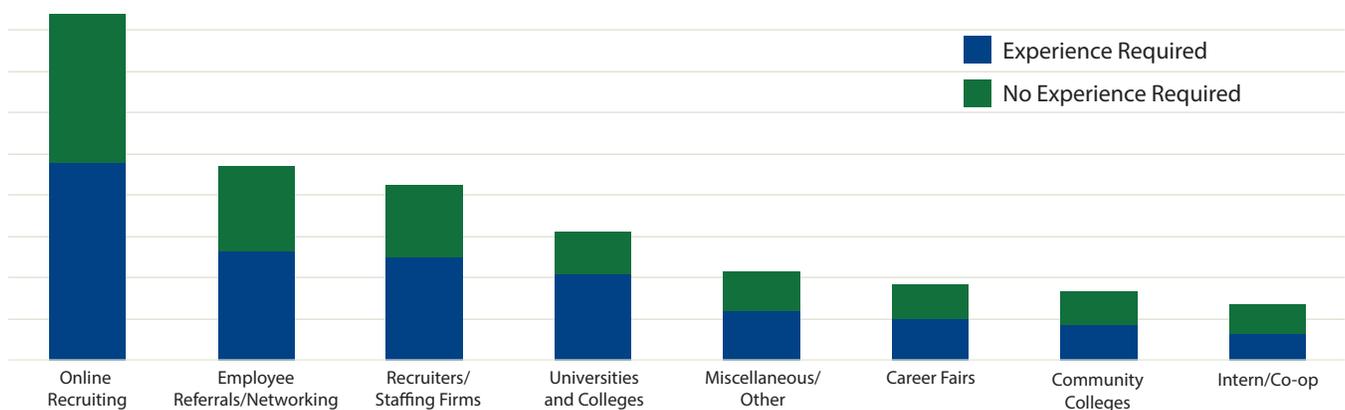
They selected answers from a range of percentages, and these percentages were given a weighted score to determine the relative use of each tool by surveyed companies. There was consistency for almost all of the recruitment tools assessed regardless of experience requirements, except universities and colleges, which were more often used to recruit positions that require experience (Figure 11). Experience is defined differently by various employers, with some lending more weight than others to internships and hands-on training provided via NCBIoImpact’s training partner programs.

### Employees Hired by Location Last Year



**Figure 10:** Survey Respondents’ Employees Hired by Location in 2018. Employees recruited from international locations (n=6) were exclusively hired for positions requiring experience.

### Recruitment Tool Ranking (Weighted)



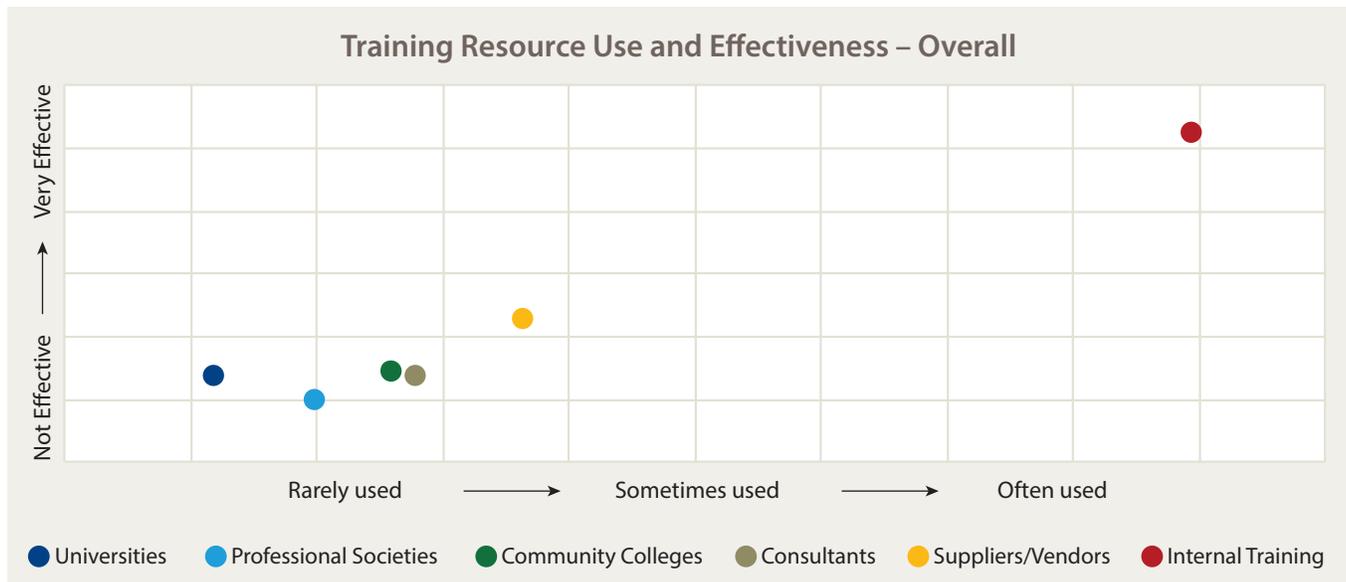
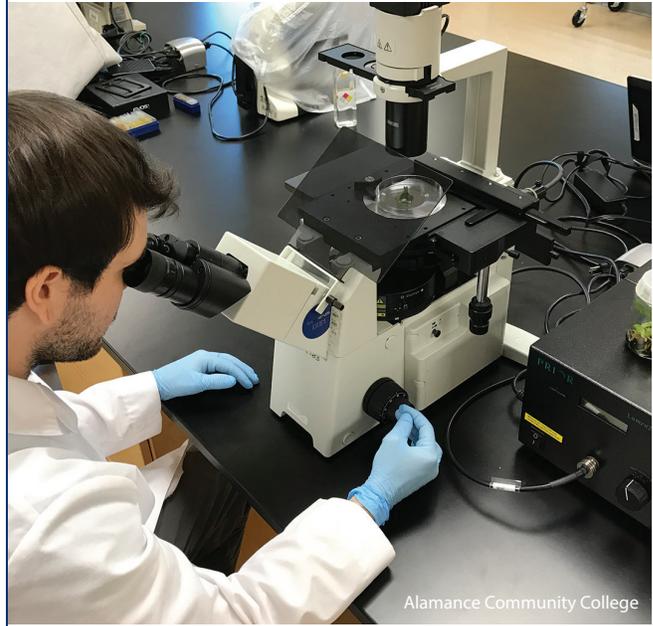
**Figure 11:** Survey Respondents’ Recruitment Tool Usage. Weighted ranks were as follows: 0-10%=1, 11-20%=2, 21-30%=3, 31-40%=4, 41-50%=5, 51-60%=6, 61-70%=7, 71-80%=8, 81-90%=9, and 91-100%=10

## Training

The final workforce issue this survey attempted to elucidate is how biopharma manufacturers prefer to train incumbent employees. To assess any variation in training mechanisms based on seniority or experience with the company, responses were categorized into the four workforce segments listed below:

- Technician/Operator
- Scientist/Engineer
- Mid-level Manager
- Senior Leadership

When averaged across all four workforce segments, internal training and suppliers/equipment vendors were identified as the top two most utilized mechanisms to meet scientific, technical, and professional development training needs in the past three years (Figure 12).

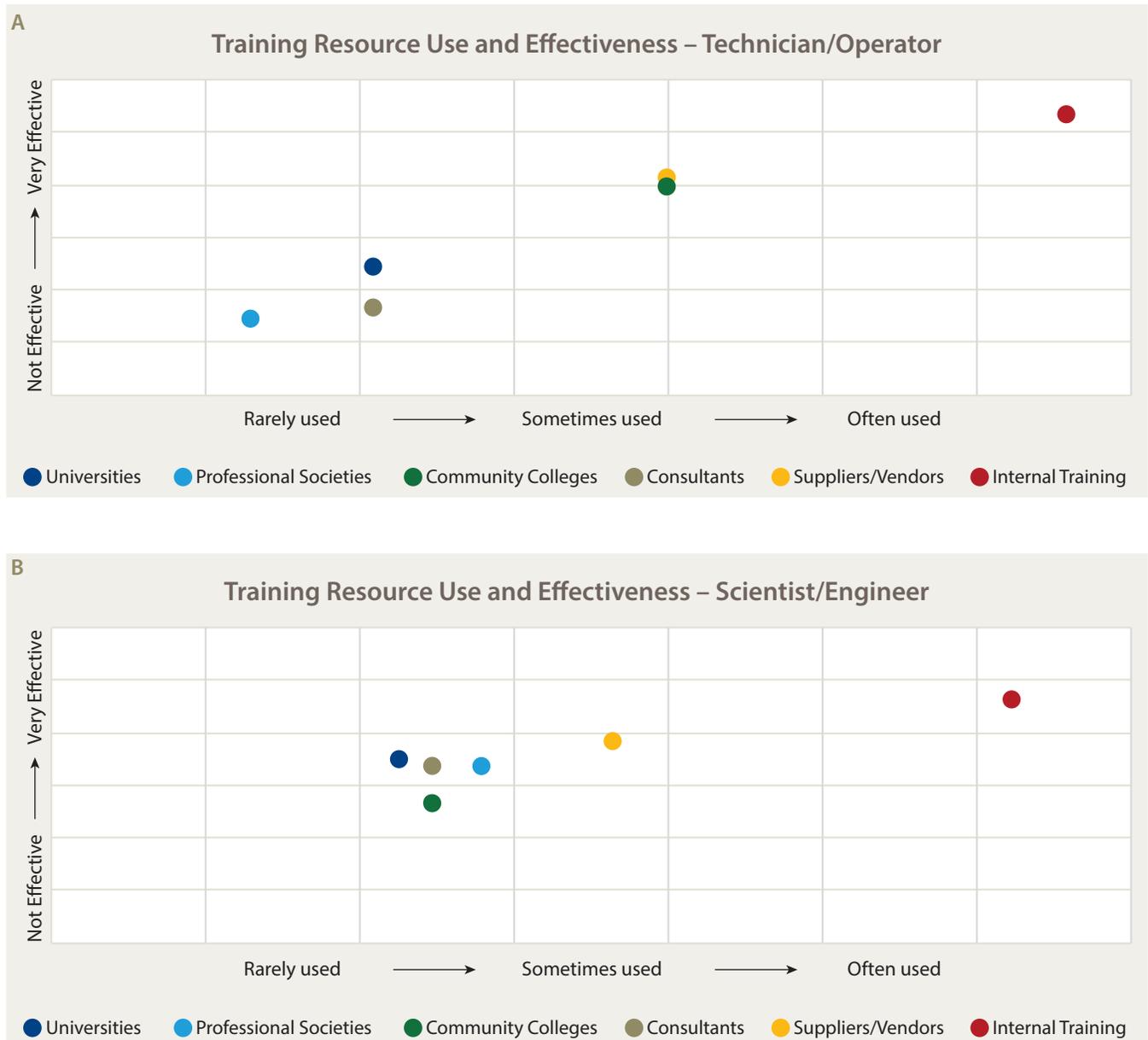


**Figure 12:** Use and efficacy of common training providers for incumbent employees across all functional areas. Weighted ranks for usage were as follows: Often=3, Sometimes=2, Rarely=1, N/A=0. Weighted ranks for effectiveness were as follows: Very Effective=3, Effective=2, Not Effective=1, N/A=0.

## Training cont'd

While internal training was the most utilized resource across all workforce segments, there was some variation in secondary tools. For example, community colleges were frequently cited for training technicians and operators

(Figure 13A), while consultants were most heavily utilized to train mid-level managers and senior leadership (Figures 13C and 13D).

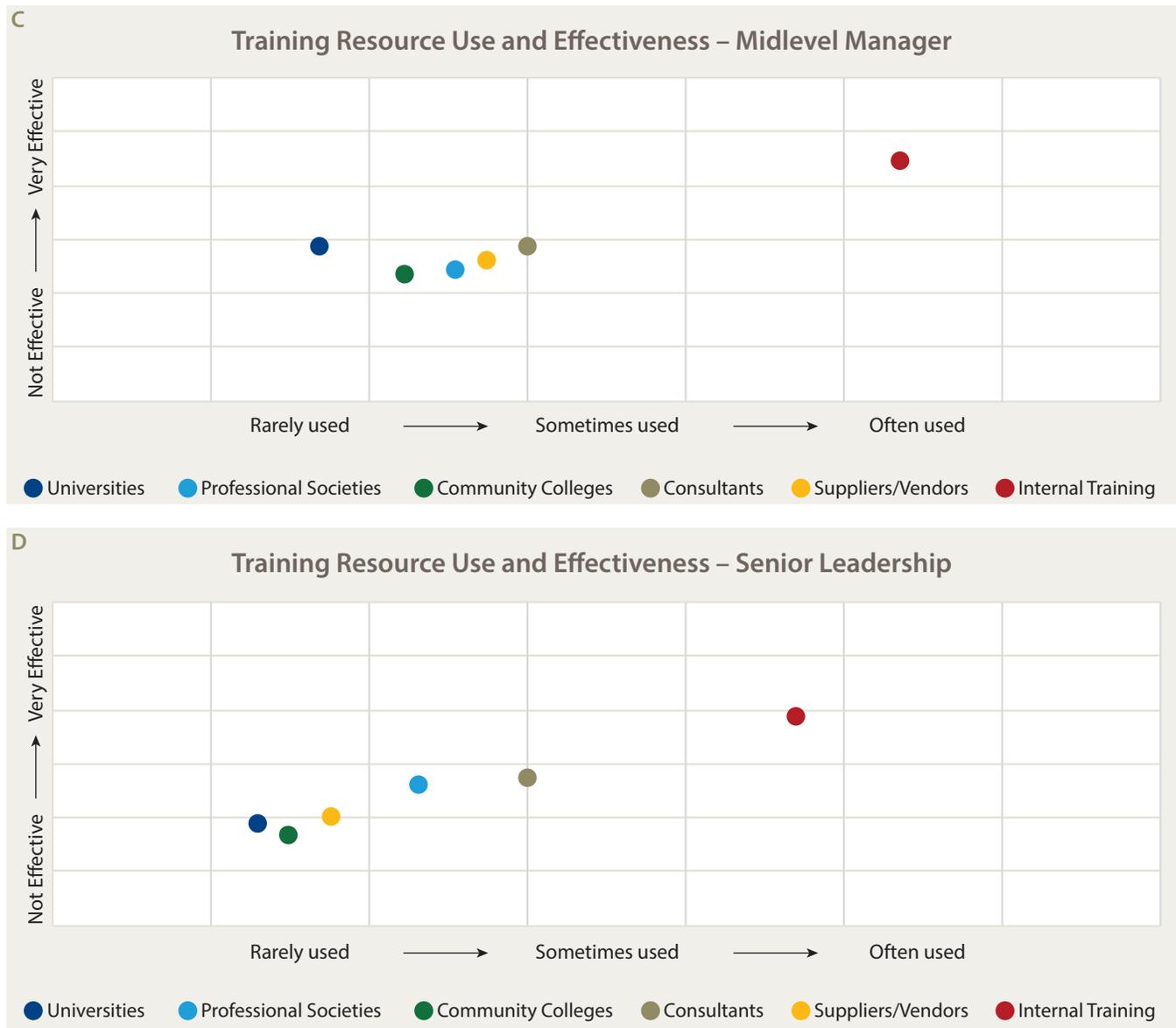


**Figure 13 (A and B):** Use and efficacy of common training providers for incumbent employees based on functional activity.

Weighted ranks for usage were as follows: Often=3, Sometimes=2, Rarely=1, N/A=0

Weighted ranks for effectiveness were as follows: Very Effective=3, Effective=2, Not Effective=1, N/A=0

## Training cont'd



**Figure 13 (C and D):** Use and efficacy of common training providers for incumbent employees based on functional activity.

Weighted ranks for usage were as follows: Often=3, Sometimes=2, Rarely=1, N/A=0

Weighted ranks for effectiveness were as follows: Very Effective=3, Effective=2, Not Effective=1, N/A=0

Not surprisingly, when asked about perceived effectiveness of these various training resources, survey respondents overwhelmingly identified internal training as most effective (Figures 12 and 13). It is worth noting that effectiveness and usage are closely correlated for all training resources (Figure 12). Considering the unique processes utilized by these companies to manufacture their products, a significant amount of internal and vendor supplied training will be required. However,

increasing the perceived effectiveness of external training mechanisms including programs at community colleges and universities will likely increase their utilization by biopharma manufacturing companies. Interestingly, despite high levels of utilization and efficacy overall, suppliers and vendors were the training resource most often cited as “not effective” for mid-level and senior leadership.

## Training cont'd

The survey also assessed how often specific training mechanisms are used by survey respondents. Onsite and online training methods were by far the most commonly used, which is consistent with a reliance on internal and vendor supplied training. Local community colleges, targeted university programs like BTEC and BRITE, and BioNetwork resources were also utilized, though the weighted use was less than half that observed for onsite and online training (Figure 14). While some differences in the utilization of tertiary resources existed between workforce segments, internal training provided onsite and online are the most prevalently used methods for training across all segments. It is important to note that these survey questions focused exclusively on the training of incumbent employees; respondents expressed satisfaction with the quality of graduates from university programs like BTEC and BRITE. While universities and community colleges have clearly demonstrated their strengths as a training ground for new employees, this data indicates they may be currently underutilized for training incumbent employees. As both content and delivery mechanisms are important to ensure implementation by local industry, this data is valuable to consider for the development of new training programs.

The survey also asked an open-ended question about the types of training needed. Technical skills such as aseptic processing and DeltaV were most often identified



Figure 15: Overall types of training needed, text size indicates response rate with larger text indicating increased frequency of the response.

as top training priorities for operator/technician and scientist positions, while soft skills like communication, leadership, and management were identified as key training areas for mid-level and senior leadership. Interestingly, digitalization, communication, and feedback were broadly identified as key training needs across all positions (Figure 15). While technical expertise is essential, employers universally emphasized in follow-up interviews

the broad importance of strong soft skills including communication, leadership, and teamwork. As a highly regulated industry, clear communication is imperative to ensure FDA compliance, successful validation and quality control, and smooth transitions between manufacturing shifts. Further corroborating the value placed on soft skills, the Coalition of State Bioscience Institutes' (CSBI) 2018 *Life Science Workforce Trends Report*

### Utilization of Training Mechanisms (Weighted)

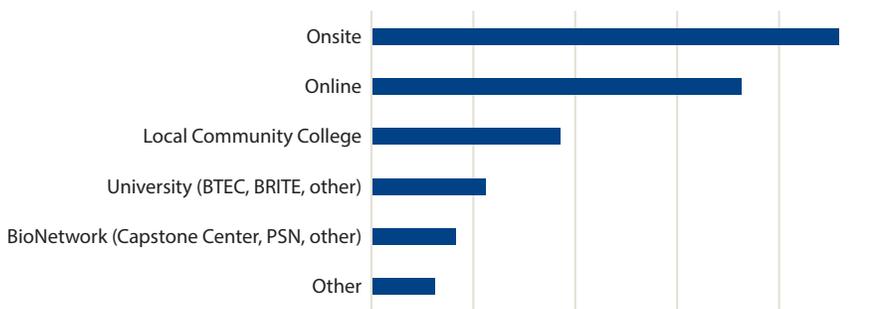


Figure 14: Survey Respondents' Use of Existing Training Mechanisms. Weighted ranks were as follows: Often=3, Sometimes=2, Rarely=1, Never=0

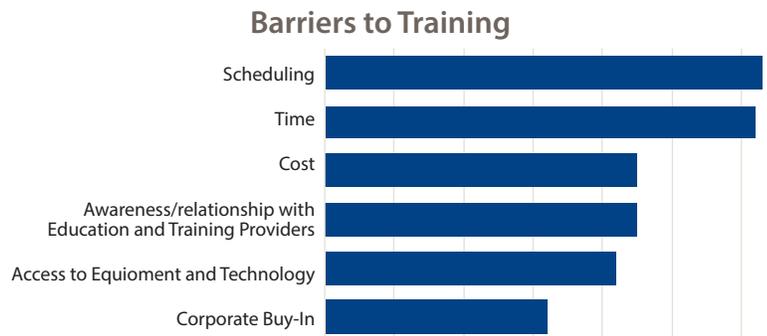
## Training cont'd

indicated that “the demand for soft skills has risen to the top as the ability to navigate in this dynamic and competitive industry has become critical.”<sup>7</sup>

Additionally, we wanted to understand barriers to training to investigate how these obstacles may be overcome moving forward to best address the types of training needed by the industry. The two most commonly reported barriers to accessing training were scheduling and time. Though little can be done to create additional time for companies to train their employees, training partners can be sure to consider time and scheduling as top priorities when designing course content and value propositions. Other barriers included cost, awareness, access, and corporate buy-in, which may be addressed with training subsidies and increased marketing by training programs and partners (Figure 16).

To deepen our understanding of the courses and equipment required to provide training to meet industry needs, company representatives were convened in two separate listening sessions focused on classical biomanufacturing and the manufacture of cell- and gene-based therapies respectively.

The classical biomanufacturing focus group communicated the value of the established NCBIoImpact training programs, including BioWork, aseptic and simulation training offered at BioNetwork’s Capstone Center and Johnston County Workforce Development Center, and degree programs and short courses offered at BTEC and BRITE. Foundational knowledge of cGMP, health and safety, preparation of materials, manufacturing operations, and skills in upstream and downstream processing remain critical competencies for the industry. Participants also reported that innovation in biomanufacturing, namely continuous manufacturing processes, single-use technologies, automation, and data analytics, has created a need for new or expanded training programs. More detail on the topics identified as critical for training entry-level employees is provided in Appendix Table 5. Additionally, companies identified key equipment for training prospective employees (Appendix Table 6).



**Figure 16:** Survey Respondents’ Barriers to Training. Weighted ranks were as follows: High=3, Medium=2, Low=1, N/A=0

The cell- and gene-based therapy focus group indicated that many of the key training topics for classical biomanufacturing, including cGMP, aseptic technique, and data analytics, are also critical for their operations. Echoing the comments of the classical biomanufacturing focus group, the hands-on training provided via BioWork, aseptic processing courses at the Capstone Center, BTEC, and BRITE were all lauded as valuable sources for qualified employees. The smaller batch sizes typically associated with manufacturing these new therapeutic products makes training with single-use technologies, aseptic welding, and other aseptic connections particularly relevant. Furthermore, time-critical processes and involvement of human cells and viral vectors make it even more essential for employees to understand and comply with safety and testing of raw materials, carefully handle in-process materials, and maintain clear communication among team members, process development engineers, and vendors. As the manufacturing processes for many cell- and gene-based therapy products continue to evolve, it is valuable for employees to have a comparatively deeper understanding of relevant technologies and biological processes. Nearly 90 subject areas were identified by participants as desired topics to prepare students for cell- and gene-based therapy work; a list of recommended equipment for training is provided in Appendix Table 7.

<sup>7</sup> Coalition of State Biosciences Institutes (CSBI). “2018 Life Science Workforce Trends Report.” Accessed September 2019. Link: [http://docs.wixstatic.com/ugd/dd6885\\_7b39782aca824539b5032acee46f2722.pdf](http://docs.wixstatic.com/ugd/dd6885_7b39782aca824539b5032acee46f2722.pdf)

# Study Analysis

## Opportunities

WoW 2020 characterized the existing biopharma manufacturing industry in North Carolina, identified key workforce challenges these companies currently face, and provided insights into opportunities for state support of this industry. As technology and processes continue to evolve, the biopharma manufacturing workforce, as well as training infrastructure, will need to evolve with it. Site visits with companies made it clear that the early 2000s investment in NCBioImpact has paid off and the existing training programs that investment created have played a critical role in facilitating the current growth of this industry in North Carolina.

Now, we are at another inflection point. The success of N.C.'s biopharma manufacturing sector and the demand it is creating for employees with previous experience is outpacing training efforts and it is time to reinvest. The WoW 2020 study has captured key information about the needs of N.C.'s biopharma manufacturing community, effectively providing a roadmap for this investment. Beyond competing with other U.S. clusters, North Carolina's training infrastructure provides a critical competitive advantage as other countries aggressively court life science companies with low tax rates and compelling incentive programs.



# Opportunities cont'd

As North Carolina's thriving biopharma manufacturing industry continues to grow, improved connectivity between biopharma companies and N.C. educational institutions is critical to address the significant hiring needs projected in WoW 2020. This connectivity will expand upon the findings of this study to inform improvements to North Carolina's already robust training infrastructure including industry awareness of existing programs and training alignment with industry needs.

WoW 2020 indicated a lack of awareness of existing community college and university training programs for incumbent employees, which leads to underutilization of these resources by N.C. biopharma manufacturers. Along with well-known entry-level training programs like BioWork, the breadth of N.C.'s higher education infrastructure also includes lesser-known specialized short courses for mid-career professionals and leadership training for management. Furthermore, it is equally imperative to increase awareness of biopharma manufacturing career opportunities among students at all levels, underrepresented populations, and transitioning military and veterans (See "*NCBiotech Veterans Outreach Program*" for pilot programs underway).

Increased awareness alone cannot meet the growing demand for highly skilled candidates. Accessibility is an important consideration to ensure training programs align with industry needs. Potential avenues to increase industry accessibility include streamlining courses to reduce classroom time and increasing the availability of hybrid and fully online courses. Additionally, biopharma companies can improve their visibility with current students by partnering with educational institutions to facilitate internships, facility tours, job fairs, and career conversations.

This will require coordination, communication, and funding for programs. NCBiotech and NC BIO are poised to facilitate these conversations, quantify the need, and identify opportunities for improvement with the help of our partners.

## Facilities and Curricula

As awareness and accessibility improve and N.C.'s biopharma manufacturing community grows, the capacity of the existing training infrastructure will be strained. North Carolina's continued support for targeted programs is imperative to maintain our position as a leader and pioneer in biopharma manufacturing workforce development in an increasingly competitive market.

## *NCBiotech Veterans Outreach Program*

Formally implemented February 2019, this program seeks to connect service members in transition, veterans, and military spouses to learning pathways and careers in the life sciences. With many shared values – discipline, honor and integrity, leadership, adaptability, attention to detail, innovative thinking, teamwork, and communication – engaging our military is not just the right thing to do, it represents a well-trained population to support biopharma's growing talent pipeline needs.

### Individual Military Internship Program

- Secured robust partnership with Fort Bragg's Soldier for Life Transition Assistance Program team
- Engaged N.C. biomanufacturers as internship hosts. Interns are already in place, working and learning in the program pilot

### BioWork Learning Workshops

- Partnered with BioNetwork STEM outreach team to create and deliver interactive adult learning platforms
- Workshops are hosted on base at Fort Bragg's Career Resource Center

### 2020 program goals:

- Obtain distinction as Army Career Skills Program organization to expand reach and create further avenues to enhance connections for industry companies, career opportunities, learning programs, and internships
- Establish partnerships with the Marine installations in Cherry Point and Camp Lejeune and expand learning workshops to additional military installations
- Expand connectivity and collaboration with related support organizations such as the USO, N.C. for Military Employment (NC4ME), Onward to Opportunity partners, and NCWorks

[www.ncbiotech.org/talent-and-careers/veterans-portal](http://www.ncbiotech.org/talent-and-careers/veterans-portal)

## Opportunities cont'd

Beyond creating partnerships, training facilities will need to upgrade and expand to stay at the cutting-edge as technologies rapidly change. Upgrades in this case include equipment, supplies, programs like DeltaV, and instructors who are intimately familiar with biopharma manufacturing processes (Appendix Tables 6 and 7). Facilities and curriculum that simulate the diverse processes happening at existing companies are paramount to training the necessary workforce to fill these roles. Additionally, existing facilities will need to be expanded and new locations may need to be established to enable industry access and accommodate the expected influx of training.

Finally, as innovative therapeutic approaches emerge, new programs will be needed. While BTEC's early action to develop a short course focused on AAV viral vector manufacturing has garnered praise and sold out enrollment, additional programming to expand these types of training opportunities throughout North Carolina are needed to complement the existing programs. Continued collaboration with industry in the development and delivery of courses is essential to ensure relevancy and reduce internal training demands. Increasing connectivity across educational institutions, from kindergarten through continuing education, will serve to introduce more North Carolinians to fulfilling careers available in the industry and enable biopharma manufacturing to continue to thrive in N.C. (See "*NCBiotech Pharma K12 Workforce Development Training Initiative*" for more information on a current program).

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## Call to Action

Biopharma manufacturing provides North Carolinians with meaningful work, competitive salaries, and opportunities for advancement that rival any industry. North Carolina's manufacturing prowess ranges from vaccines to generic pharmaceuticals to some of the first cell- and gene-based therapy products to gain regulatory approval.

We have an opportunity to raise awareness about these existing and future jobs and to inspire the next generation of the biopharma manufacturing workforce. This will take time, money, and no small amount of effort, but the benefits of this effort will far outweigh the costs. We must rise to meet this challenge to solidify North Carolina's position as a premier location for life sciences generally and biopharma manufacturing specifically. This will yield additional investment, jobs, and prosperity for the entire state for years to come.

### ***NCBiotech Pharma K12 Workforce Development Training Initiative***

**This initiative engages transitioning high school graduates, giving them a pathway to rewarding and well-paying life science jobs.**

Targeting Pitt County high school seniors interested in life sciences, this industry-led initiative creates a unique pipeline to fill jobs at local pharmaceutical companies.

Selected students are provided a 2.5-day training program at the PSN@PCC. The students work in a pilot-scale manufacturing environment with laboratory equipment to learn oral solid dosage theory and manufacturing techniques. Coursework includes weighing, milling, granulating, blending, tableting, tablet coating, and encapsulation. Upon completion, all qualified candidates are interviewed by participating companies for open positions.

#### **Criteria for eligible students:**

- High school senior in good standing and on track to graduate
- Completed National Career Readiness Certificate with minimum pre-requisite levels:
  - Applied Math – 5
  - Graphic Literacy – 4
  - Workplace Documentation – 4
- Valid driver's license and reliable transportation
- Available for full-time employment
- Able to pass a drug screening and background check

**For more information check out  
[www.ncpsn.com](http://www.ncpsn.com)**

# Appendix

**Table 1: Biologics for Clinical and Commercial Use**

Biologics are produced from living organisms or contain components of living organisms. Biologics manufactured in N.C. include vaccines, industrial enzymes, purified proteins from human blood, diabetes therapeutics, regenerative medicines, and cell- and gene-based therapies.

Company	County
Ajinomoto North America	Wake
Archer Daniels Midland Co.	Brunswick
AveXis Inc.	Durham
Avoca Inc.	Bertie
Biogen	Wake
BioResource International Inc.	Durham
bluebird bio Inc.	Durham
Cellectis	Wake
FUJIFILM Diosynth Biotechnologies USA Inc.	Wake
Grifols	Johnston
Hemo Bioscience Inc.	Durham
Humacyte Inc.	Wake
Huvepharma Inc.	Scotland
Ingredion Inc.	Forsyth
KBI Biopharma Inc.	Durham
KBI Biopharma Inc. (Process Development Facility)	Durham
Keratin Biosciences Inc.	Forsyth
Medicago USA Inc.	Durham
Merck & Co. Inc.	Durham

Company	County
Nitta Gelatin NA Inc.	Cumberland
Novex Innovations LLC	Forsyth
Novo Nordisk Pharmaceutical Industries LP	Johnston
Novozymes North America Inc.	Franklin
Pfizer Inc.	Lee
Precision BioSciences Manufacturing Center for Advanced Therapeutics	RTP
Promethera Biosciences LLC	Durham
Sagent Pharmaceuticals	Wake
Seqirus, a CSL Company	Wake
Stallergenes Greer	Caldwell
Twin City Bio LLC	Forsyth
Vertellus Specialties Inc.	Guilford
White Labs Inc.	Buncombe
ZenBio Inc.	Durham
Zoetis Inc.	Durham

## Appendix cont'd

### Table 2: Biologics for R&D

Biologics for R&D include antibodies, media, and other products manufactured in a cGMP or similar environment to be used for research purposes.

Company	County
Avioq Inc.	Durham
Cygnus Technologies LLC	Brunswick
EpiCypher Inc.	Durham
ImmunoReagents Inc.	Raleigh
Lonza RTP	Wake
MOLTOX	Watauga

### Table 3: Traditional Pharmaceuticals and Diagnostics

Traditional pharmaceuticals and diagnostics manufacturers produce small-molecule prescription drugs that are chemically synthesized, rather than being produced by living organisms. Traditional pharmaceuticals include oral solid dose, parenteral, and inhaled products.

Company	County
Alcami	New Hanover
Almac Clinical Services LLC	Durham
Aurobindo Pharma USA Inc.	Durham
Baxter Healthcare Corp.	McDowell
BD Diagnostics	Durham
BD Diagnostics	Alamance
Biogen (Oral Solid Dose Facility)	Durham
bioMérieux Inc.	Durham
Cambrex High Point	Guilford
Catalent Pharma Solutions LLC	Wake
CMP Pharma Inc.	Pitt
Exela Pharma Sciences LLC	Caldwell
Fresenius Kabi USA LLC	Wilson
G&W Laboratories LLC	Lincoln
Glenmark Pharmaceuticals Inc., USA	Union
GSK	Wake
Guerbet LLC	Raleigh
Mallinckrodt Pharmaceuticals	Wake
Mayne Pharma USA	Pitt

Company	County
MEDTOX Diagnostics Inc.	Alamance
Merck & Co. Inc.	Wilson
Novo Nordisk	Durham
Pfizer Inc.	Nash
PharmAgra Labs Inc.	Transylvania
Pisgah Labs Inc.	Transylvania
Princeton Laboratories	Mecklenburg
Procter & Gamble	Guilford
Purdue Pharmaceuticals LP	Wilson
Qualicaps Inc.	Guilford
Relion Manufacturing Inc.	Buncombe
Sandoz Inc., a Novartis Division	Wilson
Sterling Pharma USA LLC (fka CiVentiChem)	Wake
Tergus Pharma LLC	Durham
Thermo Fisher Scientific	Pitt
Thermo Fisher Scientific	Guilford
United Therapeutics Corp.	Durham

## Appendix cont'd

### Table 4: Supplements and Nutraceuticals

Supplement and nutraceuticals manufacturers produce non-prescription pharmaceutical alternatives including dietary supplements and food additives.

Company	County
BestCo Inc.	Iredell
Daily Manufacturing Inc.	Rowan
Gaia Herbs Inc.	Transylvania
Nutra-Pharma Manufacturing Corp. of N.C.	Davidson

### Table 5: Topics Considered Essential for Entry-Level Classical Biomanufacturing Employee Training

Essential Topics
Continuous manufacturing
Single-use technology
How to grow cells (bacteria, fungi, plant cells, animal cells).
Virology
Antibodies
Protein synthesis (in vivo) and protein purification.
Microbiology
Aseptic technique
cGMP knowledge & reasoning (why)
Filter use (integrity)
Overview of the industry
Functions of a company and interaction
Communication/interacting with others.
Documentation
Troubleshooting
Overall view of how the many aspects and controls work together to maintain control of the environment.
Cell culture experience (testing)
Pipetting
Microbial Awareness

## Appendix cont'd

**Table 6: Equipment Needed for Training in Classical Biomanufacturing Operations**

Upstream	Fill-Finish, Capping & Inspection
Suspension cell bioreactors	Filling machine
Adherent cell bioreactors	Vial/Syringe Washer
Biosafety cabinets	Mixers
Electroporators	Component Sterilizer
Single use bioreactors	Isolator
Single use technologies including aseptic welders	Laminar air flow hood
Fermentors for microbial fermentation	Biosafety cabinets
Biosafety cabinets	Airborne particle counter
Incubators	Airborne viable counter
Freezer/refrigerators	Process support equipment
Spectrophotometer	Mixers (could be stainless steel or single use, with single use being preferable)
Downstream	Buffer storage equipment - the need for this would depend on scale of operations
Centrifuge for cell recovery/clarification – disc-stack unit would be preferable	Clean-in-place equipment - again, the need would depend on scale
Tangential flow microfiltration equipment for clarification	Filter integrity tester
Single use technologies including aseptic welders	Autoclave
Depth filtration system for clarification	Glasswasher
Chromatography system for product purification	Single use technologies including aseptic welders
Tangential flow ultrafiltration system for product concentration, formulation	
Bulk filling equipment (many options here)	
UV/Vis spectrophotometer	
Conductivity meters	
pH meters	

## Appendix cont'd

**Table 7: Equipment Needed for Training in Cell and Gene-based Therapy Manufacturing Operations**

<b>General</b>	
Cell culture equipment	
Suspension cell bioreactors	
Adherent cell bioreactors	
Biosafety cabinets	
Single use bioreactors	
Single use technologies including aseptic welders	
<b>Upstream</b>	
Rocker bioreactors for mammalian cell culture (single use)	
Appropriate control units for fermentors, bioreactors	
Cell Counter (such as a Vi-CELL)	
Microscope	
Tubing welder	
Biosafety cabinets	
Incubators	
Freezer/refrigerators	
<b>Downstream</b>	
Depth Filtration system for clarification	
Chromatography system for product purification	
Tangential flow ultrafiltration system for product concentration, formulation	
Bulk filling equipment (many options here)	
UV/Vis spectrophotometer	
Conductivity meters	
pH meters	
Freezer/refrigerators	
	<b>Fill-Finish</b>
	Fill machine - many sizes and varieties
	Isolator
	<b>Process support equipment</b>
	Mixers (could be stainless steel or single-use, with single-use being preferable)
	Buffer storage equipment - the need for this would depend on the scale of operations
	Plate reader
	High-performance liquid chromatography system (HPLC)
	qPCR system
	Various smaller miscellaneous items for measurements such as endotoxin, bioburden, ELISAs, protein quantification, host cell protein quantification, host cell DNA quantification, etc.

## North Carolina Biotechnology Center

The North Carolina Biotechnology Center is a private, non-profit corporation that transforms North Carolina's life science opportunities into economic prosperity through innovation, commercialization, education and business growth. It's headquartered in the Research Triangle Park, with regional offices in Asheville, Charlotte, Greenville, Wilmington and Winston-Salem.

[ncbiotech.org](http://ncbiotech.org)



NCBIO advocates for state and federal public policies that encourage the growth of life science companies, supports the development of a strong life science workforce, promotes research and technology transfer at universities and other institutions including support for capitalization and commercialization of products.

[ncbioscience.net](http://ncbioscience.net)